

केन्द्रीय मुहर विभाग-2

संदर्भ -: केमूवी-2/16: 17945

27 03 2026

विषय: IS 17945 : 2022 के amendment no. 1 के अनुपालन के दिशानिर्देश।

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशानिर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

**हरीश मीना
वैज्ञानिक-सी**

प्रमुख (केमूवी 2)

सभी क्षेत्रीय/शाखाकार्यालय/प्रयोगशालाएँ/FAD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16:17945

27 03 2026

Subject: Guidelines for implementation of amendment no. 1 to IS 17945 : 2022.

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

**Harish Meena
Scientist-C**

Head (CMD-2)

All ROs/BOs/Labs/FAD/LRMD

CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 17945

27 03 2026

Subject: Guidelines for implementation of amendment no. 1 to IS 17945 : 2022 (Food for Special Medical Purpose Intended for Infants — Specification).

1. Amendment no. 1 to IS 17945 : 2022 has been published. The last date of implementation of the amendment is **14th June 2026**.
2. The significant changes in the standard through this amendment as listed in the Table are given for the purpose of general guidance.

Clause No.	Change
5.12 & Table 2	<ul style="list-style-type: none">• “IS 5403” has been removed from the method of Test column of “Yeast and Mould count” test parameter.• “ISO 15213” has been substituted with IS 18349 (Part 1) under method of Test column of “Sulphite reducing Clostridia” test parameter.• “ISO 22964” has been substituted with “IS 18357” under method of Test column of “Enterobacter sakazakii (Cronobacter sp.)” test parameter.• New Requirement of “E.coli” test parameter has been introduced.
5.16.1.5	<ul style="list-style-type: none">• Test method of detection of Bacterial and Fungal toxins i.e. “IS 5887 (Part 5)” has been substituted with “IS 5887 (Part-5/Sec 1)”.

3. Consequent upon the issuance of the amendment, the existing product manual has been revised which is being circulated separately.
4. The guidelines for implementation of the amendment are given below:

A. LICENSEES:

- i) All Licensees shall implement the amendment by **14th June 2026**. Any difficulty in implementation shall be brought to the notice of CMD-2 at the earliest but in any case at least 30 days before the last date of implementation. BOs shall ensure that no Licences are under operation as per IS 17945 : 2022 without considering the amendment No. 1 after **14th June 2026**. The status of implementation of the amendment shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.
- ii) Licensees shall submit evidence of conformity to the Amended & Additional requirements through In-house/Independent Test Reports as well as revised declaration of test equipment as per Form 2. Verification of implementation of the amendment, wherever required, shall be done through a surveillance visit within 30 days of confirmation of implementation of the amendment to standard by licensee.
- iii) If the Licensee fails to complete all actions by **14th June 2026** it shall be dealt with as per the prevailing guidelines.

B. APPLICATIONS FOR GRANT OF LICENCE:

- i. Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed without considering the amendment no. 1. However, if the Applicant is desirous of considering the Application as per the amended Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking from such Applicants shall also be obtained that if the sample fails while considering the provisions of the amended Standard, Licence will not be granted by BIS without considering the amendment no. 1.
- ii. Applications which are recorded henceforth may be processed with or without considering the amendment no. 1. Processing of Applications without considering the amendment No. 1 shall be permitted only up to **13th June 2026** and for such cases Applicant shall give a declaration that they will implement the amended Standard by **14th June 2026**.
- iii. Beyond **14th June 2026** no Licence shall be granted without considering the amendment no. 1.

C. CHANGE IN SCOPE OF LICENCE:

- i. For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
- ii. However, processing of such applications for change in scope of licence without considering the amendment No. 1 shall be permitted only up to the date of implementation of the amendment by the licensee or up to **14th June 2026**, whichever is earlier.

6. The above guidelines come into force with immediate effect.

**Harish Meena
Scientist-C**

**Head (CMD-2)
DDG (Certification)**